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EXAMINER	
MAICHER, MICHAEL D	

ART UNIT	PAPER NUMBER
3687	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/594,993	GAUBATZ ET AL.	
	Examiner	Art Unit	
	MICHAEL MAICHER	3687	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the subject matter in claims 1 or 12 must be shown. No new matter should be entered.
2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
3. Further, Examiner requests that the drawings be labeled with text rather than numbers for clarification and understandability.

Specification

4. Arrangement of the specification: As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, with underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

    (a) TITLE OF THE INVENTION.
    (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
    (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
    (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
    (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
    (f) BACKGROUND OF THE INVENTION.
        (1) Field of the Invention.
        (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
    (g) BRIEF SUMMARY OF THE INVENTION.
    (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
    (i) DETAILED DESCRIPTION OF THE INVENTION.
    (j) CLAIM OR CLAIMS (commencing on a separate sheet).
    (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
    (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date as follows: Examiner objects to the content of the specification. Specifically, the specification contains disclosures that were not present in the application from which the Applicant claims priority. Clarification is required.

Claims

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **Claims 1 is rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

   6.1. Specifically, claim 1 recites the limitation "module" which only appear to be recited, not explained, in the specification. The word "module" can refer to any number of things such as hardware or software. Given that the word is undefined in the specification and cannot be definitively limited from its use in context, Examiner finds that without undue experimentation the term module cannot be used. See also MPEP 2164.01(a).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claims 1, 2, and 11 are rejected** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8.1. Specifically, claims 1 and 11 recite the limitation "and/or" which renders the claim indefinite because it makes it unclear whether the limitation following the "and/or" is included in the claimed matter.

8.2. Specifically, claim 2 recites the limitation "typical" which renders the claim indefinite because, by definition, typical refers to a representative specimen of a group, but here the group has not been defined, therefore there cannot be a specimen representative of it.

9. Examiner finds that claim 12 recites the element "means for" which is a limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function.

Applicant may:

(a) Amend the claim so that the claim limitation will no longer be interpreted as a limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant should clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 103

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. **Claims 1-21 are rejected** under 35 U.S.C. 103(a) as being unpatentable over **Moeller** (British Medical Journal, see attached article) and **Flagg** (6,456,979).

12. Regarding claim 1: A computer-aided method for automated risk parameter identification and/or characterization, where relative risk values for a multiplicity of products and/or populations are determined, characterized
12.1. in that product and/or population data records stored accessibly in databases (2) are taken as a basis for generating a lookup table (4) containing risk parameters,

12.1.1. **Moeller** shows a population data of a specific type.

12.1.2. **Flagg** demonstrates the use of databases as well as the use of specific embodiments of server software that support the functionality of lookup tables (**database 250, Fig. 12** and **Column 23, lines 22-35**).

12.2. in that a filter module (3) is used to store risk classes in association with the product and/or population data records on the basis of the risk parameters from the lookup table (4),

12.2.1. **Moeller** shows risk classes in association with population data with a risk parameters, such as cancer types (**Table**).

12.3. in that an analysis module (1) is used to generate at least one expected value for a probability of occurrence of a definable risk event for each risk class and to store it in association with the risk event,

12.3.1. **Moller** shows a table with the expected rate of occurrence for the relative risk (**Table, see also ¶3**; where expected occurrence and relative risk ratio of cancer in Denmark for period 1977-89 is shown).

12.4. in that a normalization module (5) is used to normalize the expected value for the respective risk class on the basis of an average rate of occurrence of the event for the product and/or population data records to produce a relative occurrence parameter, and

12.4.1. **Moller** shows in the same table as before an average rate along with the expected rate (**Table**). The actual operation of dividing one number by another to determine a ratio is old and well known in the art and can be performed by common computer programs, such as Microsoft **Excel** 2003 (hereafter **Excel**).

12.5. in that the analysis module (1) is used to produce a risk characterization value for the respective risk class on the basis of the comparison of the relative occurrence parameters, with the risk characterization value determining the probability of occurrence of the risk event.

12.5.1. **Moller** shows the relative ratio of different types of cancer are compared, and

Examiner finds that the linkage to a multiplicity of products is the Applicant's

intended use and therefor does not have to be in the prior art reference (¶4). Further, the actual act of comparing the numbers are old and well known in the art and could be performed by **Excel**.

12.6. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the references because **Flagg's** system of evaluating life insurance policies can be improved with the added assessments of **Moeller's** calculations. Specifically, using the statistical assessments in **Moeller** would enable **Flagg** to then evaluate insurance policies for the occurrence of risks in large cohorts of patients, further adding another tool of evaluation and enhancing the assessment.

13. Regarding claim 2: *The method as claimed in claim 1, characterized in that, for a specific combination of risk classes, a risk characterization value is determined using the analysis module (1) and is compared with available empirical data records for the purpose of characterizing the product and/or the population, where only typical risk characterizations situated within a definable threshold value are associated with the risk class.*
13.1. See Examiner's rejection of claim 1 for determining a risk characterization value. Further, **Flagg** discloses comparisons to industry standards, which Examiner reads as functionally equivalent to "*risk characterization... is compared with available empirical data records*"(**Fig. 2 step 70**).

14. Regarding claim 3: *The method as claimed in either of claims 1 and 2, characterized in that one or more of the risk classes have an associated multiplicity of risk parameters, where the method is repeated with the risk parameters modified and the deviations from the expected values are stored in association with the risk classes.*
14.1. See Examiner's rejection of claim 13.

15. Regarding claim 4: *The method as claimed in one of claims 1 to 3, characterized in that the analysis module (1) is used to determine correlation factors between the risk parameters on the basis of the population data files divided into risk classes and to store them in association with the relevant risk parameters.*

15.1. Moeller shows a relative risk ration, which was calculated based on population data from a specific group of participants in a study (**Table**). Further, while the step to "store" is not recited, it is obvious to one skilled in the art at the time of the invention that the relative risk ratio, which is a relative risk parameter, is the by product of the population data divided into risk classes (cancer types **Table**).

16. Regarding claim 5: *The method as claimed in one of claims 1 to 4, characterized in that one or more threshold values are used to allocate each risk parameter a relevance flag for a particular population and/or product.*
16.1. Marking, or flagging, a value, or any other type of data, if it satisfies a threshold is old and well known in the art and can be demonstrated by a program such as Excel using the "if/then" functionality.

17. Regarding claim 6: *The method as claimed in one of claims 1 to 5, characterized in that the lookup table (4) containing risk parameters is generated at least partly dynamically on the basis of product and/or population data records stored accessibly in databases (2).*
17.1. **Flagg** discloses the use of Microsoft SQL 2000, Oracle data base server, Microsoft Windows 2000 Advanced server, or Datacenter, which are old and well known systems of varying capabilities (**Column 23, lines 22-35**); Combined, these systems can offer the functionality of having a lookup table that can be generated dynamically on the bases of other information (such as population data used in **Moeller, Table**). Flagg discloses risk parameters, which could be used in the lookup table mentioned above (such as gender risk class in **Fig. 2, step 70**).

18. Regarding claim 7: *The method as claimed in one of claims 1 to 6, characterized in that for secondary risk groups at least one separate relative occurrence parameter is generated.*
18.1. **Moeller** discloses a plurality of risk groups all with separate relative risks, which Examiner finds to be sufficiently similar to relative occurrence parameter (**Table**).

19. Regarding claim 8: *The method as claimed in one of claims 1 to 7, characterized in that when the data are compared with the empirical data stored in relevant memory units (6) the data, if situated outside of a determinable fluctuation tolerance, are aligned with the empirical data.*
    19.1. The storage, comparison, and analysis of data are all old and well known concepts in the art and could be performed by a program such as Excel. Examiner has read "*fluctuation tolerance*" to mean a range that can fluctuate, which is also old and well known in the art.

20. Regarding claim 9: *The method as claimed in one of claims 1 to 8, characterized in that the risk parameters comprise at least the relative mortality risks.*
    20.1. **Flagg** discloses a mortality matrix, which Examiner reads as functionally equivalent to relative mortality risks (**Abstract**).

21. Regarding claim 10: *The method as claimed in one of claims 1 to 9, characterized in that new risk classes are produced dynamically on the basis of at least parts of the relative occurrence parameters.*
    21.1. **Flagg** discloses a health-based risk class, which Examiner reads as describing a number of possible risk classes, which was generated in part by some aspect of (**Column 15, lines 46-60**).

22. Regarding claim 11: *The method as claimed in one of claims 7 to 10, characterized in that the secondary risk groups comprise at least sex and/or age of occurrence and/or smoker/non-smoker and/or policy duration.*
    22.1. **Fragg** discloses identifying a gender based risk class, which Examiner views to be sufficiently similar to a secondary risk group of sex (**Fig. 2, step 60** and related description).

23. Regarding claim 12: *A computer-aided system for automated determination of relative risks which are linked to a multiplicity of financial products, comprising:*
    23.1. *a) means for identifying one or more risk classes which are associated with the multiplicity of financial products;*

23.1.1. **Flagg** teaches the step of "identifying a gender-based risk class for a given policy to be evaluated" associated with a policy, a financial product, which Examiner views as *one or more risk classes* (**Fig. 2, step 60** "gender based risk class", **step 80** "lifestyle/health profile base risk class", and related descriptions). However, **Flagg** does not teach the remainder of claim 1's elements.

23.2. *b) means for determining an expected rate of occurrence for each risk class;*
23.2.1. **Moller** shows a table with the expected rate of occurrence for the relative risk (**Table, see also ¶3**; where expected occurrence and relative risk ratio of cancer in Denmark for period 1977-89 is shown).

23.3. *c) means for dividing the expected rates of occurrence by an average rate in order to determine a relative risk ratio for each risk class; and*
23.3.1. **Moller** shows in the same table as before an average rate along with the expected rate (**Table**). The actual operation of dividing one number by another to determine a ratio is old and well known in the art and can be performed by common computer programs, such as Microsoft **Excel** 2003 (hereafter **Excel**).

23.4. *d) means for comparing the relative risk ratios for the purpose of characterizing the relative risks linked to the multiplicity of products.*
23.4.1. **Moller** shows the relative ratio of different types of cancer are compared, and Examiner finds that the linkage to a multiplicity of products is the Applicant's intended use and therefor does not have to be in the prior art reference (**¶4**). Further, the actual act of comparing the numbers are old and well known in the art and could be performed by **Excel**.

23.5. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the references because **Flagg's** system of evaluating life insurance

policies can be improved with the added assessments of **Moeller's** calculations. Specifically, using the statistical assessments in **Moeller** would enable **Flagg** to then evaluate insurance policies for the occurrence of risks in large cohorts of patients, further adding another tool of evaluation and enhancing the assessment.

24. Regarding claim 13: *The computer-aided system as claimed in claim 12, characterized in that said one or more risk classes are associated with one or more criteria, and which additionally has means for modifying one or more criteria and for recalculation of the relative risk ratio for determining an effect of said modification on the relative risks which are linked to the products.*
    24.1. **Flagg** discuses risk classes based on gender and lifestyle/health profiles, where Examiner has interpreted the profiles to be a type of criteria (**Fig. 2** and related description). The remainder of the claim merely repeats the steps of claim 1 in their calculation.

25. Regarding claim 14: *The computer-aided system as claimed in either of claims 12 and 13, characterized in that one or more of said risk classes are linked to different criteria, and in which said relative risk ratios are used for comparing said risk classes.*
    25.1. **Flagg** teaches where risk classes are based on gender and lifestyle/health criteria, which Examiner views as a risk class is linked to different criteria (**Fig. 2** and related description). However, **Flagg** does not teach the remainder of the claim.
    25.2. **Moeller** teaches relative risk rations are used to compare said risk classes, the step of using the relative risk ratio to redefine one or more of said risk classes and the step of determining a separate relative risk ratio for sub-groups of risks (**Table, Relative Risk column, page 1, paragraph 4**, where relative ratio of different types of cancer risks are compared).
    25.3. See Examiner's rejection of claim 1 for the reason to combine the references.

26. Regarding claim 15: *The computer-aided system as claimed in one of claims 12 to 14, characterized in that it comprises means for applying the relative risk ratio to redefining one or more of said risk classes.*
26.1. **Moeller** demonstrates that relative risk ratio's can be used to compare, and redefine a risk class in the calculations performed in their study **(Table, Relative Risk column, page 1, paragraph 4**, where relative ratio of different types of cancer risks are compared). Further, the means for such a calculation are old and well known and could be performed by Excel.

27. Regarding claim 16: *The computer-aided system as claimed in one of claims 12 to 15, characterized in that it comprises means for determining a separate relative risk ratio for risk subgroups.*
27.1. See Examiner's rejection of claim 12, as the arguments apply here as well since the act of determining a relative risk ratio will not change. Further, Examiner reads the determination of a ratio for one group is functionally equivalent for developing one for a risk subgroup.

28. Regarding claim 17: *The computer-aided system as claimed in one of claims 12 to 16, characterized in that for use in determining the relative risk ratios it comprises means for storing data which relate to the predominance of criteria which are linked to said risk classes.*
28.1. **Flagg** discloses a means for storing risk class data, and the remainder of Applicant's claim merely declares the intended use of the storage function **(Fig. 1, column 23, lines 23-29**; where server stores insurance prevalence criteria as shown in **Fig. 2**).

29. Regarding claim 18: *The computer-aided system as claimed in one of claims 12 to 17, characterized in that it comprises means for comparing the predominance data with empirical industrial data for particular combinations of criteria and means for aligning the stored data with the empirical data.*
29.1. **Flagg** discloses comparisons to industry standards, which Examiner reads as functionally equivalent to "*means for comparing the predominance data with empirical*

industrial data for particular combinations"(**Fig. 2 step 70**). Also, Examiner finds that "*means for aligning the stored data with the empirical data*" is functionally equivalent to well known methods of the manipulation and comparison of data, and can be performed by common programs such as **Excel**.

30. Regarding claim 19: *The computer-aided system as claimed in one of claims 12 to 18, characterized in that it comprises means for storing data which relate to the expected rates of occurrence for the purpose of use when determining the relative risk ratios.*
30.1. See Examiner's rejection of claim 17; specifically, Examiner finds no difference in view of the prior art of the step of storing one type of data versus another.

31. Regarding claim 20: *The computer-aided system as claimed in one of claims 12 to 19, characterized in that it comprises means for comparing the stored data with empirical industrial data and means for aligning the stored data with the empirical data.*
31.1. See Examiner's rejection of claim 18; specifically, Examiner finds no difference in light of the prior art of the function of the claim where the only difference is the type of data.

32. Regarding claim 21: *The computer-aided system as claimed in one of claims 12 to 20, characterized in that the one or more risk classes are associated with at least one criterion, and also containing means for using the relative risk ratio to determine the effect which the inclusion in a risk class of one or more risks which do not meet one or more criteria linked to this risk class has on this risk class.*
32.1. Moeller discloses risk classes, relative risk ratios, and criteria from which they used to perform their study. Specifically, the table goes through a number of risks/criteria from which a relative risk ratio is calculated (**Table**).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Guberan et al. (see attached article from International Journal of

Epidemiology, 1998) discloses a study that contains key concepts related to probabilities, ratios, expected and observed results, and discusses at length the methods in which such calculations are made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL MAICHER whose telephone number is (571)270-3195. The examiner can normally be reached on Monday through Thursday, 10AM to 3PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Gart can be reached on 571-272-3955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

/Matthew S Gart/

Supervisory Patent Examiner, Art Unit 3687